

# EXHIBIT 31

Via Electronic Submission

The Honorable Katherine M. Hiner  
Acting Secretary  
U.S. International Trade Commission  
500 E Street, S.W.  
Washington, D.C. 20436

Re: *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv.  
No. 337-TA-1276

To the International Trade Commission,

My name is Michael A.E. Ramsay, MD, FRCA, and I am the Chief Executive Officer of the Patient Safety Movement Foundation (“PSMF”). I have served on the board of PSMF since 2013. I am also Chairman Emeritus of the Department of Anesthesiology and Pain Management at Baylor University Medical Center in Dallas, Texas, and I serve as a member of the Baylor University Medical Center Board of Trustees.

As the Past Director of Anesthesia for the liver transplant program at Baylor, I have personally provided anesthesia for over 1,000 transplant recipients. As part of my prior practice, I first learned about Masimo’s life-changing technologies. I was privileged to meet Masimo’s founder, Joe Kiani, soon after he founded Masimo. I was impressed with his tremendous drive to create technology that will make our healthcare systems safer. In 2014, Joe continued these efforts by creating the Patient Safety Movement Foundation, a non-profit aimed at reducing the 200,000 preventable deaths in U.S. hospitals each year to zero. I now lead that organization. We aim to achieve zero preventable patient harm and death across the globe by 2030.

On behalf of PSMF, I write in support of the recommended orders in the Commission’s investigation regarding Apple’s unfair importation of watches containing pulse-oximetry functionality. PSMF believes that devices like the Apple Watch, which do not offer hospital-grade pulse oximetry functionality, are potentially dangerous to the public, particularly given Apple’s historic marketing of the feature. Consumers will believe based on this advertising that the Apple Watch will provide them with accurate and clinically relevant information. This is especially true given Apple’s public perception as a technology giant. If Apple says the device measures blood oxygen saturation, most consumers will not question that.

The Apple Watch Series 6 was launched in Fall of 2020 in the midst of the COVID-19 pandemic. Reports suggested starting in 2020 that COVID-19 had a fairly significant effect on the body’s ability to oxygenate blood.<sup>1</sup> This led to sales of fingertip pulse oximeters increasing 500% during a single week in February 2020 and by mid-May the devices were sold out in many stores.<sup>2</sup>

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<sup>1</sup> [https://www.washingtonpost.com/lifestyle/wellness/pulse-oximeter-covid-19-coronavirus/2020/05/18/5b6f8a98-96df-11ea-9f5e-56d8239bf9ad\\_story.html](https://www.washingtonpost.com/lifestyle/wellness/pulse-oximeter-covid-19-coronavirus/2020/05/18/5b6f8a98-96df-11ea-9f5e-56d8239bf9ad_story.html)

<sup>2</sup> *Id.*

Apple's launch of the Series 6 capitalized on this market demand.<sup>3</sup> Apple's launch video featured Dr. Sumbul Ahmad Desai, MD, the VP of Health at Apple. In the video she was asked to talk "about blood oxygen and its importance to your health."<sup>4</sup> She stated:

Blood oxygen saturation also known as SpO<sub>2</sub> is like a vital sign. It's a key measurement that contains critical information about your breathing and circulation. Apple Watch is already a powerful health tool with apps that measure heart rate and hear rhythm and now adding blood oxygen brings another valuable health measurement to users. Blood oxygen and pulse oximetry are terms that we've heard a lot about during the COVID pandemic. As you breathe your heart and lungs work together to deliver oxygen throughout your body. Blood oxygen saturation is an indication of how well this system is functioning and of your overall respiratory and cardiac health and pulse oximetry is how you measure it.<sup>5</sup>

Apple's touting of the device during the COVID pandemic, despite the fact it has not been shown to provide clinically meaningful data to patients, posed a risk to any individual who sought to use the device as a way of protecting themselves from the adverse consequences of COVID. The risk is highlighted by Masimo's recent White Paper related to its Masimo W1 healthwatch, which contained a study comparing the Masimo W1 to the pulse oximeter in the Apple Watch Series 7.<sup>6</sup>

As shown in Table 6 of the White Paper—reproduced below, the Adjusted ARMS for the Apple Watch was below what is required for FDA clearance, while the Masimo W1 achieved clinically relevant results showing it functions at a hospital-grade level.

Table 6. Tabulated Summary of Performance Statistics for Masimo W1 and Apple Watch

	Bias (%)	Precision (%)	ARMS (%)	Adjusted Precision (%)	Adjusted ARMS (%)
Masimo W1	0.2	1.5	1.5	1.6	1.6
Apple Watch	3.1	3.2	4.4	3.4	4.6

Moreover, unlike the Apple Watches with pulse-oximetry functionality, the Masimo W1 offers continuous monitoring of SpO<sub>2</sub>. This is incredibly important. Rapid blood-oxygen desaturations are a serious problem and often occur when someone is sleeping. For example, it can occur due to the effects of sleep apnea. Masimo's study indicates the Masimo W1 successfully "catches" these dips in oxygen saturation, while the Series 7 barely functions due to its non-

<sup>3</sup> <https://www.youtube.com/watch?v=YKQFaPRObp8> ("Apple Watch Series 6! Watch the full reveal here")

<sup>4</sup> *Id.* at 2:36-2:42.

<sup>5</sup> *Id.* at 2:42-3:28

<sup>6</sup> [https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A\\_Whitepaper\\_Masimo\\_W1\\_US\\_v4.pdf?v=1670952306](https://cdn.shopify.com/s/files/1/0097/9809/0814/files/PLM-14384A_Whitepaper_Masimo_W1_US_v4.pdf?v=1670952306) ("White Paper")

continuous monitoring and its need to be positioned perfectly. This is shown in Table 7 of the White Paper reproduced below:

Table 7. Tabulated Summary of Fast Desaturation Events and Detection Rates for Masimo W1 vs Apple Watch

Test Configuration	Number of Subjects	Number of Valid Events	Detection Rate for Masimo W1	Detection Rate for Apple Watch
Configuration 1	7	49	49/49=100%	3/49=6.1%
Configuration 2	8	60	60/60=100%	4/60=6.7%

Detection Rate = (Nt / Ndesat) x 100 (%), Nt = Number of Detected Event by Test Device, Ndesat = Number of All Valid Fast Desaturation Events by Reference SpO2

In my opinion, this data indicates that the blood oxygen sensor in the Apple Watch does nothing beneficial for the public welfare.

It is also not clear that any of the other features of the Apple Watch offer a net benefit to the public health. Although I have read anecdotal reports of people with Apple Watches believing it led to them getting checked out for a heart issue or it contacted authorities after a crash, it is not clear whether these beneficial incidents are counteracted by the significant false positives. To the extent the watch is alerting authorities when there is no danger or sending users to emergency rooms when they are perfectly healthy, there is a huge societal cost.

It is my understanding that the Apple Watch has been criticized for these false positives with respect to numerous of its apps. For example, a recent article in the New York Times criticized the crash detection features and indicated it was creating a heavy burden on 911 operators in certain parts of the country.<sup>7</sup> The Journal of the American Medical Informatics Association, also published a study concluding that false positives from the Apple Watch “may lead to overutilization of healthcare resources.”<sup>8</sup> The study concluded “The Food and Drug Administration and Apple should consider the unintended consequences of widespread screening for asymptomatic (“silent”) atrial fibrillation and use of the Apple Watch abnormal pulse detection functionality by populations in whom the device has not been adequately studied.”<sup>9</sup>

The cost of a “false positive,” is difficult to calculate. A single errant 911 call might only cost a few minutes of an operator’s time. But, it could also lead to first responders being unavailable to provide life-saving treatment to an actual crash victim. There is also the emotional toll of a patient believing they have a serious heart condition, only to find out it was false.

A broken clock might be right twice a day, but when caring for patients you need a clock that works. That is what PSMF seeks to achieve in healthcare, and that is what Masimo’s innovations have helped the healthcare industry move to. I fear that investment in these life-saving technologies might cease if companies like Apple are allowed to infringe the intellectual property rights of innovative companies like Masimo without consequence. It is in the public interest to protect these creators and accordingly, an exclusion order will benefit the public welfare and further PSMF’s goals to rid the world of preventable medical errors.

<sup>7</sup> <https://www.nytimes.com/2023/02/03/health/apple-watch-911-emergency-call.html>

<sup>8</sup> <https://academic.oup.com/jamia/article/27/9/1359/5911974?login=false>

<sup>9</sup> *Id.*

Best regards,

A handwritten signature in black ink, appearing to read "Michael Ramsay MD". The signature is fluid and cursive, with the letters "M", "R", and "M" being prominent. The "MD" is written in a smaller, more distinct font at the end of the signature.

Michael Ramsay, MD